caTIS5.0 Model

START

Patients

- **PatientID**
- Lname
- Fname
- Mname
- DOB
- Race
- Gender
- OtherMalig
- FHX
- OtherFHX

Admissions

- **AdmissionID**
- **PatientID**
- StudyNum
- **StudyID**
- **TrackID**
- HospAdmNum
- *CancerTypeID*
- DXDate
- *DzStatus*
- Surg
- Phys
- SurgPathNum

Specimens

- **SpecimenID**
- **AdmissionID**
- RcvDate
- **RcvdLocID**
- **CollectorID**
- *TissueSiteID*
- TissueSide
- *TissueTypeID*
- *ProcessID*
- Size
- RcvdQA
- ConfirmDate
- **ConfirmByID**
- NeoCell
- Necrosis
- Lymph
- TotCell
- HistQual
- SampMade
- Avail
- Storage
- Unit
- Box
- ResAcc

Samples

- **SampleID**
- **SpecimenID**
- SynthDate
- *SampTypeID*
- Conc
- Integ
- GelNum
- LaneNum
- Amount
- Storage
- Unit
- Box
- Dist

NAArrays

- **ArrayID**
- SynthDate
- Array Type
- Copies
- Conc
- WellVolume
- Enzyme
- Primer

SampArray

- **ArrayID**
- **Position**
- **SampleID**

ClinEvent

- **EventID**
- Date
- **PatientID**
- *EventTypeID*
- EventTypeValue

Studies

- **StudyID**
- StudyTitle
- StudyPI
- StudyOpen
- StudyClose
- IRB

DistSamples

- **DistributionID**
- **SampleID**
- Amount
- Charge

TMA

- **ArrayID**
- SynthDate
- Sections Cut

PathData

- **AdmissionID**
- *PathDXID*
- Size1
- Size2
- Size3
- Grade1
- Grade2
- Grade3
- Inv1
- Inv2
- Inv3
- Inv4
- Inv5
- Marker2
- Necrosis
- LymphResponse
- Nodes
- PosNodes
- T
- N
- M
- Stage
- NonMalig1
- NonMalig2
- NonMalig3
- Marker1

Institutions

- **InstitutionID**
- InstName
- InstCode
- Address1
- Address2
- City
- State
- Zip
- CoordName
- CoordPhone
- CoordFax
- CoordEmail

Pathologists

- **PathologistID**
- Lname
- Fname
- Institution
- Phone
- Fax

DistSpecs

- **DistributionID**
- **SpecimenID**
- Amount
- Charge

SpecArray

- **ArrayID**
- **Position**
- **SpecimenID**

DistTMA

- **DistributionID**
- **ArrayID**
- Amount
- Charge

Investigators

- **InvestigatorID**
- Lname
- Fname
- Institution
- SCCMember
- Dept
- StudyName
- IRB
- Funding
- Phone
- Email

Comments

- **CommentID**
- **SpecimenID**
- Date
- *Comment*
- Initials

Distributions

- **DistributionID**
- DistDate
- **DistInvestigator**

Tracking

- **TrackID**
- SendRcv
- Date
- Carrier
- CarrierTrackNum
- **StudyID**
- **InstitutionID**
- Comment

DistNAArray

- **DistributionID**
- **ArrayID**
- Amount
- Charge

KEY

Object Tables in Bold

MetaData Tables in Italics

HIPAA Identifiers in Red

Table Keys in Bold Underline

Controlled Vocabulary Fields in Blue Italics
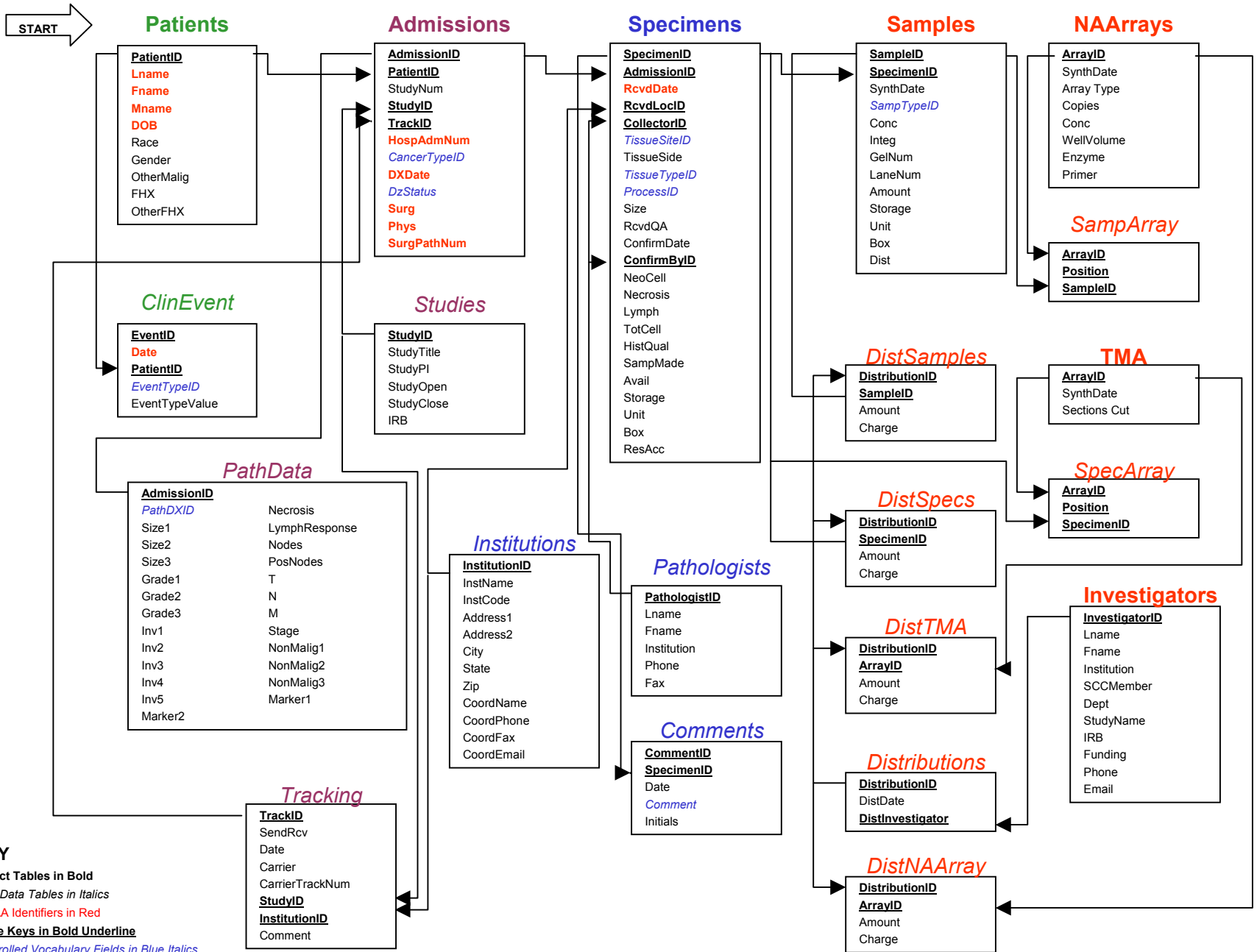
I. Possible Solutions / Models

    A. All sites use their existing systems; mapping tools developed to connect each system to a grid.
- i. Inefficient
- ii. Each site has varying degrees of system development
- iii. However, may only be a limited number of existing systems?

    B. All sites use existing system; mapping tools developed to transfer data to a common system (central repository- "GenBank Model").
- i. Inefficient / Synchronization issues
- ii. Still need multiple mapping tools
- iii. However, each site could maintain 'control' of their own data locally

    C. All sites adopt a common system
- i. Many sites can't / won't change their existing system
- ii. Each site may have different, specific needs of a system

    D. >> Two tiered approach- Large legacy systems develop mapping tools / interfaces to connect to the grid; small or non-existent systems replaced by caBIG foundation software (caTISSUE Lite)
- i. Sites can keep their existing systems at the cost of developing appropriate interfaces
- ii. Incentive to adopt new caBIG foundation software is that all subsequent modules will be 'plug and play'

II. 'High Level' Project Plan
    A. Draft project charter (Developers)
    B. Draft detailed project plan (Developers)
    C. Charter / plan approved (All WS members)
    D. Gather data on existing systems (All WS members)
- i. Each adopter responsible for intelligence gathering of systems
- ii. Gather
  1. Use Cases
  2. Object Models
  3. CDE / Vocabularies
  4. User Interfaces
  5. Usable Code
- iii. Formal report presented at 11/04 meeting
- iv. Systems
  1. Academic
     a. UPMC
     b. MSKCC
     c. Vanderbilt
     d. CALGB / SWOG / NSABP / ECOG
     e. EDRN

           f. CHTN
           g. Others
       2. Commercial
           a. Ardais
           b. LabTrack
           c. Freezer Works
    v. This step does not need to be complete before proceeding

E. Draft white paper on IRB / MTA Issues (All WS members)
    i. Work with DSIC WS
       1. Institutional IRBs
       2. Central IRB / DHHS / NCI / PRIMR
       3. Institution tech transfer offices
       4. Industry representatives
    ii. IRB
       1. Overview of key IRB concerns and how caTISSUE system will address these
           a. What are the concerns
           b. Use cases for where confidentiality could be problematic
           c. De-identification / encryption schemes
           d. Multi-level access
       2. Template of protocol / consent forms that would be considered 'caBIG-compliant.'
    iii. MTA
       1. Overview of key MTA/DSIC concerns and how caTISSUE system will address these
           a. What are the concerns
           b. Use cases for where DSIC could be problematic
           c. Multi-level access
    iv. This step does not need to be complete before proceeding

F. CaTISSUE Lite Development (WU / Indiana / Jefferson)
    i. Draft Use Cases
       1. Incorporate data from intelligence gathering
    ii. Draft System Architecture
       1. Incorporate data from intelligence gathering
       2. Coordinate with Arch WS
    iii. Draft Object Model / Data Model
       1. Incorporate data from intelligence gathering
    iv. Identify CDEs and Vocabularies (with UPMC)
       1. Incorporate data from intelligence gathering
       2. Coordinate with CDE WS
       3. Gather basic CDEs for caTISSUE Lite; other CDE classes can be developed on a module by module basis as needed
    v. Design Use Cases
    vi. Approval of Final Design Document (all WS members)
    vii. Implement Object Model / Data Model
    viii. Implement Use Cases

         ix. Draft Test Cases
          x. Perform Testing
         xi. Deployment to Server (WU / Adopters)
        xii. Integration Testing
       xiii. End User testing
       xiv. Deploy to Production
        xv. Draft User / Developer / Installation Guides
       xvi. Publish

G. caTIES Development (UPMC / Penn / ?)
      i. ????????????????
H. SDK / API Development for Existing Systems (UPMC / NW / ?)
      i. ????????????????
I. Draft Design Documents for Additional caTISSUE Modules – Past Year 1
J. Draft Additional SDK/API for Additional Systems to Integrate – Past Year 1

A, B, C to be completed immediately (< 4 weeks)
D-H to run concurrently
      D should be complete much prior F
      E can run concurrently
      F and G need to be coordinated
            caTIES module should plug-in to caTISSUE Lite
      F and H need to be coordinated
            CDE / Arch for each must be identical